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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/610,489 07/05/00 CHERUKURI

S 24224

HM12/0327

EXAMINER

FUBARA, B

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1030 15TH STREET NW
WASHINGTON DC 20005

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/27/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/610,489

Applicant(s)

CHERUKURI, SUBRAMAN RAO

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 9-12, 24 and 25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for therapeutic composition, does not reasonably provide enablement for "preventative composition." The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The asserted utility is not believable on its face. It is not known how a method wherein a composition is claimed can be administered to prevent or act as a prophylaxis for a medical condition that may have began. It is not known how the occurrence of a pending medical condition requiring treatment can be precisely predicted in a subject as to when and how the condition will occur and to administer the claimed composition to prevent the occurrence.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1404 (CAFC, 1988):

- 1) Breadth of claims.
- 2) Nature of invention.
- 3) State of prior art.

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- 4) Level of ordinary skill in the art.
- 5) Level of predictability in the art.
- 6) Amount of direction and guidance provided by the inventor.
- 7) Existence of working examples
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The present invention is in the field of therapeutic delivery of a composition wherein the composition comprises binders, salivating agents, diluents and active agents.

The state of the art is what prior art knows about the invention. There is no known art wherein a certain composition is administered to successfully prevent a medical condition before the occurrence.

The level of ordinary skill is high but only in the art of delivering therapeutic composition for treating medical conditions. The predictability or lack thereof in the art refers to the ability of one skilled in the art to extrapolate the disclosed or known results to the claimed invention. The lower the predictability, the higher the direction and guidance that must be provided by the applicants. In the instant invention the predictability is very low and consequently, the need for the higher levels of direction and guidance by the applicants. However, the amount of direction and guidance provided by the applicants is limited to therapeutic composition. There is no evidence in the specification that established correlation between the experiment and the claimed utility. See Ex parte Mass, 9 USPQ2d 1746, 1987. The quantity of experimentation required to use the method as claimed in the instant invention,

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based on applicants' disclosure would be undue burden because, one of ordinary skill in the art would have to perform significant amount of in-vivo experiments as well as assays.

4. Claims 1-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-30 recite "semi-solid" composition. It is unclear what the applicants mean by "semi-solid." Applicant did not describe in the text what "semi-solid" is.

"Absence of free water" in lines 10 and 11 of claim 1 is indefinite.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 4-7, 9-15, 18-21 and 23-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raiden et al. (US Patent No. 5,840,334).

The instant invention is directed to a composition and a method of preparing the composition wherein the composition comprises a binder (0.01-70% by weight), salivating agent (0.05-15% by weight), diluent or bulking agent (10-90% by weight) and an active material (0.001-70% by weight).

Raiden et al. discloses a composition and a method of making the composition wherein the composition comprises hydrogenated vegetable oils (binder, 0-10% by weight); sodium chloride, lecithin, propylene glycol (salivating agents); xylitol, mannitol, sorbitol, starch, lactose

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(diluent/bulking agents, 0.5-25% by weight); and active materials namely: ibuprofen, acetaminophen, anti-inflammatories, appetite suppressants, mineral supplements, nutritional additives, calcium carbonate, cocoa butter, cod liver oil, and sesame oil. Raiden et al. teaches that chewable antacid composition that can dissolve quickly can be made from the composition. See abstract, column 1, line 62 to column 2 and line 16, column 3, line 5 to column 4 and line 30, column 5, column 8, line 10 to column 11 and line 63, examples I-III and claims 1-30. The prior art differs from the instant invention in that the prior art fails to teach the composition in amounts of the ranges disclosed by the instant application. However, one of ordinary skill in the art would know routine experimental procedures to mix the parts of the composition to arrive at an acceptable composition that would dissolve quickly (column 10, lines 7-10). Applicant provided no data regarding the criticality of the weight percentages of the parts of the composition.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Raiden et al. One having ordinary skill in the art would have been motivated to prepare a composition that would dissolve quickly as suggested in the prior art.

7. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
March 21, 2001

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

